510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

in Accordance with SMDA of 1990

ABC CERVICAL PLATING SYSTEM

February 11, 2000

COMPANY: Aesculap®, Inc.
1000 Gateway Blvd.
So. San Francisco, CA 94080

CONTACT: Lia S. Jones, Regulatory Associate
650-624-5073 (phone)
650-589-3007 (fax)
lia.jones@aesculap.com (email)

TRADE NAME: ABC Cervical Plating System

COMMON NAME: Anterior Cervical Screw Spinal Fixation System

DEVICE CLASS: Class II

PRODUCT CODE: 87 KWQ

CLASSIFICATION: 888.3060 – Spinal Intervertebral Body Fixation Orthosis

REVIEW PANEL: Orthopedic Devices Branch
Division of General and Restorative Devices

DEVICE DESCRIPTION

The ABC Cervical Plating System consists of two spinal implant components: bone plates and self-locking bone screws. The implants are manufactured from titanium alloy, Ti6Al4V (according to ISO 5832/3) and are provided non-sterile. The specialized ABC instruments are made primarily of surgical grade stainless steel (according to ISO 7153/1) and are hand-held, re-usable devices.

INDICATIONS FOR USE

The ABC Cervical Plating System is intended for the treatment of cervical spine instability resulting from degenerative disc disease (defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies), trauma (including fractures), post-traumatic kyphosis or lordosis, tumors, and re-operation for failed previous fusions. Levels of anterior cervical intervertebral body screw fixation for this indication are from C2-T1.

WARNING: This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
in Accordance with SMDA of 1990

ABC CERVICAL PLATING SYSTEM

February 11, 2000

PERFORMANCE DATA

No applicable performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act for this device system.

The ABC implants subject to this 510(k) submission, however, were put through various test methods in accordance to applicable ISO / ASTM standards in order to establish their safety and efficacy. The results indicate that the modified and new implants are substantially equivalent to the predicate devices.

SUBSTANTIAL EQUIVALENCE

The new and modified components described in this premarket notification are substantially equivalent to those in Aesculap's current ABC Cervical Plating System (K974706) with regard to intended use, fundamental scientific technology, design, and material.

In addition, the following predicate anterior cervical plating systems recently received FDA clearance for similar device modifications and system expansions:

- AcuFix™ Anterior Cervical Plate System (K990005)
- ATLANTIS™ Anterior Cervical Plate System (K993855)
- Blackstone™ Anterior Cervical Plate System (K974885)
- Osteonics ACCP System (K982798, K992344)

These competitor systems are substantially equivalent to the modified ABC Cervical Plating System with regard to intended use, material composition, labeling, implant size and design.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 14 2000

Ms. Lia S. Jones
Regulatory Associate
Aesculap, Inc.
1000 Gateway Boulevard
South San Francisco 94080-7028

Re: K000486
Trade Name: ABC Cervical Plating System
Regulatory Class: II
Product Code: KWQ
Dated: February 11, 2000
Received: February 14, 2000

Dear Ms. Jones:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Donna R Lachman

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K000486

Device Name: **ABC Cervical Plating System**

Indication for Use:

The ABC Cervical Plating System is intended for the treatment of cervical spine instability resulting from degenerative disc disease (defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies), trauma (including fractures), post-traumatic kyphosis or lordosis, tumors, and re-operation for failed previous fusions. Levels of anterior cervical intervertebral body screw fixation for this indication are from C2-T1.

WARNING: This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diana R. Vachon

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000486

Prescription Use X or Over-the-Counter Use _____

(per 21 CFR 801.109)

(Optional Format 3-10-98)